

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

Bio-Rad Laboratories, Inc.,

NO. C 02-05946 JW

Plaintiff,

v.

**ORDER GRANTING PARTIAL
SUMMARY JUDGMENT**

Applera Corporation, et al.,

Defendants.

I. INTRODUCTION

This is a patent dispute. Plaintiff, Bio-Rad Laboratories, Inc. (“Bio-Rad”), owns United States Patent No. 5,089,111 (“’111 patent”) and asserts that certain products made by Defendant, Applera Corporation (“Applera”), infringe one or more claims of the ’111 patent.

The motion presently before the Court is for partial summary judgment. Applera requests partial summary judgment that the chemical, polyacrylamide, is not an equivalent to “a substantially linear polymer selected from the group consisting of methyl cellulose, hydroxypropyl methyl cellulose, hydroxyethyl methyl cellulose, and hydroxybutyl methyl cellulose.” ’111 patent, 12:22-25. Applera argues that Bio-Rad, is estopped from asserting infringement by the doctrine of equivalents because Bio-Rad made a narrowing amendment to its claims in response to a rejection based on patentability. Bio-Rad disputes Applera’s Motion and maintains that its amendment does not preclude it from asserting infringement by the doctrine of equivalents.

The Court held oral argument on November 29, 2004. The parties, with this Court's approval, stipulated to multiple stays proceedings, including staying a decision on Applera's Motion for Partial Summary Judgment. On March 2, 2005, the Court conducted a case management conference. The parties then informed the Court that they were no longer in settlement negotiations, and thus, requested the Court to proceed with its decision on the pending motion. Based on all of the submissions and arguments to date, the Court GRANTS Applera's Motion for Partial Summary Judgment.

II. BACKGROUND

Bio-Rad filed U.S. Patent Application No. 07/303,174 ("174 application") with the United States Patent and Trademark Office (the "PTO") on January 27, 1989. The '174 application initially contained 27 claims and was entitled, "Electrophoretic Sieving in Gel-Free Media with Dissolved Polymers." Initially filed claims 1 and 27 were the only independent claims. Of these 27 initially filed claims, initially filed claim 1 and initially filed claim 27 are relevant to this discussion.

Initially filed claim 1 of the '174 application read as follows:

1. A method of separating a mixture of sample ions of varying molecular weights in a sample into components, said method comprising electrophoretically passing said sample through a separation column containing a gel-free aqueous solution of a substantially linear polymer having a molecular weight of about 10,000 to about 2,000,000, said molecular weight being within a range of about 0.1 to about 200 times the average molecular weight of said macromolecular species in said mixture, the concentration of said polymer in said solution being sufficient to retard the flow of said species through said separation column to degrees which vary with the molecular weights of said species.

Garber Decl., Exh. 1, ABBR065864. Initially filed claim 27 of the '174 application read as follows:

27. A method of separating a mixture of polynucleotide chains in a sample, said polynucleotide chains each containing from about 10 to 10,000 base pairs, said method comprising electrophoretically passing said sample through a capillary column containing a gel-free aqueous solution of a substantially linear polymer selected from the group consisting of methyl cellulose, hydroxypropyl methyl cellulose, hydroxyethyl methyl cellulose, and hydroxybutyl methyl cellulose, said polymer characterized in terms of the viscosity of a 2% aqueous solution thereof being within a range of about 1,000 centipoise to about 10,000 centipoise at 25°C, and the concentration of said polymer in said solution is from about 0.1% to about 0.5% by weight.

Id. at ABBR065868.

The PTO examiner rejected initially filed claims 1-13 of the '174 application as obvious under 35 U.S.C. § 103 in light of the Tietz, et al., Electrophoresis in Uncrosslinked Polyacrylamide Molecular

1 Sieving and its Potential Applications, Electrophoresis, 7 1986, 217-220 (“Tietz”) and Bode, SDS-
 2 Polyethyleneglycol Electrophoresis: A Possible Alternative to SDS- Polyacrylamide Ge Electrophoresis,
 3 FEBS Lettes, 65(1) (1976) at 56-58 (“Bode”). The examiner stated that because Tietz “successfully
 4 performed molecular sieving experiments using non-crosslinked linear polyacrylamide” claims 1-13 would
 5 be obvious to the person having ordinary skill in the art. Id. at ABBR065889. In the same office action,
 6 the examiner allowed initially filed claim 27 without comment.

7 In response to the office action, Bio-Rad amended initially filed claim 1 to read:

8 1. A method of separating a mixture of sample ions of varying molecular weights in
 9 a sample into components, said method comprising electrophoretically passing said sample
 10 through a separation column containing a gel-free aqueous solution of a substantially linear
 11 water-soluble cellulose derivative polymer having a molecular weight of about 10,000 to
 12 about 2,000,000, said molecular weight being within a range of about 0.1 to about 200
 13 times the average molecular weight of said sample ions [macromolecular species] in said
 14 mixture, the concentration of said polymer in said solution being sufficient to retard the flow
 15 of said species through said separation column to degrees which vary with the molecular
 16 weights of said species.

17 Id. at ABBR065894-95 (double underlined text indicates addition; bracketed text indicates deletion)
 18 (amendment indicia in original). Initially filed claim 27 was unchanged. After Bio-Rad’s amendment to
 19 initially filed claim 1, the PTO examiner issued a Notice of Allowability.

20 Following the Notice of Allowability Bio-Rad abandoned the ’174 application in favor of a
 21 Continuation-in-Part application (“CIP”). Notably, the CIP retained the title of the ’174 application, an
 22 amended version of initially filed claim 1, and the original version of initially filed claim 27. The CIP issued
 23 as the ’111 patent on February 18, 1992.

24 Amended claim 1 of the abandoned ’174 application was again altered in the newly filed CIP.

25 Claim 1 of the CIP read:

26 1. A method of separating a mixture of sample ions of varying molecular weights in
 27 a sample into components, said method comprising electrophoretically passing said sample
 through a separation column containing a gel-free aqueous solution of a water-soluble
 polymer selected from the group consisting of cellulose derivatives, saccharide-based and
 substituted saccharide-based polymers, polysilanes, polyvinylalcohol and
 polyvinylpyrrolidone, said polymer having a molecular weight of about 10,000 to about
 2,000,000, said molecular weight being within a range of about 0.1 to about 200 times the
 average molecular weight of said sample ions in said mixture, the concentration of said
 polymer in said solution being sufficient to retard the flow of said species through said

1 separation column to degrees which vary with the molecular weights of said species.

2 Id. at ABBR065950. Initially filed claim 27 from the '174 application was retained, unchanged, as claim
3 16 of the CIP. The PTO issued a Notice of Allowability for the CIP without any rejections.

4 However, the PTO included a Statement of Reasons with its Notice of Allowability. The Statement
5 of Reasons recognized that no prior art taught or fairly suggested practicing the method of separating a
6 mixture of sample ions described in claim 1 or claim 16 of the CIP application. Garber Decl., Exh. 3,
7 ABBR065974-75. The examiner recited claims 1 and 16 of the CIP application and underlined the (1)
8 "electrophoretically passing" and (2) "said molecular weight being within a range of about 0.1 to about 200
9 times the average molecular weight of said sample ions in said mixture" language of claim 1. Id. The
10 examiner also underlined the (1) "the group consisting of methyl cellulose, hydroxypropyl methyl,
11 hydroxyethyl methyl cellulose, and hydroxybutyl methyl cellulose," (2) "the viscosity of a 2% aqueous
12 solution thereof being within a range of about 1,000 centipoise to about 10,000 centipoise at 25°C," and
13 (3) "the concentration of said polymer in said solution is from about 0.1% to about 0.5% by weight"
14 language of claim 16. Id. Bio-Rad made no comment on the examiner's Statement of Reasons and the
15 '111 patent issued from the CIP application.

16 Bio-Rad filed the present lawsuit against Applera on December 26, 2002. Applera manufactures
17 various performance optimized polymers ("POP") that are used for molecular sieving. Applera's POP
18 products contain polydimethylacrylamide ("PDMA") and combinations of PDMA and polyacrylamide.
19 Bio-Rad claims that the polyacrylamide and PDMA in Applera's POP products represent equivalents to
20 claim 16 of the '111 patent. Thus, according to Bio-Rad, Applera's POP products infringe claim 16 of the
21 '111 patent.

22 Applera counters that prosecution history estoppel precludes Bio-Rad from asserting the doctrine
23 of equivalents against Applera's polyacrylamide-containing POP products. Applera asserts that Bio-Rad's
24 amendment to initially filed claim 1 in the '174 application was to overcome a rejection related to
25 patentability. Applera notes that initially filed claim 27 contained the same objectionable limitation as
26 initially filed claim 1, that is, "a gel-free aqueous solution of a substantially linear polymer." Applera argues,
27 however, that the PTO allowed initially filed claim 27 without amendment because initially filed claim 27
28

was limited on its face to a discrete group of chemicals not including polyacrylamide. Thus, Applera asks the Court to find that Bio-Rad's amendment to initially filed claim 1 should also preclude the assertion of infringement against Applera's polyacrylamide-containing POP products by doctrine of equivalents as to initially filed claim 27, now claim 16 of the '111 patent.

III. STANDARDS

Summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The non-moving party "must set forth specific facts showing that there is a genuine issue for trial." Fed. R. Civ. P. 56(e). To preclude the entry of summary judgment, the non-moving party must bring forth material facts, i.e., "facts that might affect the outcome of the suit under the governing law Factual disputes that are irrelevant or unnecessary will not be counted." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986).

The construction of patent claims is a question of law for the Court. See Markman v. Westview Instruments, Inc., 517 U.S. 370, 384 (1996). Likewise, the question of whether prosecution history estoppel applies is a matter of law for the Court to decide. Glaxo Wellcome, Inc. v. Impax Laboratories, Inc., 356 F.3d 1348, 1351 (Fed. Cir. 2004). As such, a question of prosecution history estoppel is properly decided on a motion for summary judgment. Id. The moving party "is entitled to summary judgment [on prosecution history estoppel] only if the facts and inferences, when viewed in the light most favorable to [the non-moving party], would not persuade a reasonable jury to return a verdict for . . . the nonmoving party." Id. (citing Anderson, 477 U.S. at 255).

"According to the Supreme Court in Festo, 'a narrowing amendment made to satisfy any requirement of the Patent Act may give rise to an estoppel.'" Glaxo, 356 F.3d at 1351-52 (quoting Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 736 (2002) (Festo VIII)). The estoppel is presumptive and may be rebutted if the patentee can show "[1] that the alleged equivalent could not reasonably have been described at the time the amendment was made, or [2] that the alleged equivalent was tangential to the purpose of the amendment, or [3] that the equivalent was not foreseeable (and thus

not claimable) at the time of the amendment.” Glaxo, 356 F.3d at 1532 (citing Festo VIII, 535 U.S. at 740-41). An equivalent is foreseeable if the patentee can “show that at the time of the amendment one skilled in the art could not reasonably have been expected to have drafted a claim that would have literally encompassed the alleged equivalent.” Festo VIII, 535 U.S. at 733.

An amendment to one claim may “infect” another claim with estoppel. Glaxo, 356 F.3d at 1356. The Federal Circuit Court of Appeals (“FCCA”) has recognized “that subject matter surrendered via claim amendments during prosecution is also relinquished for other claims containing the same limitation.” Id. The “rule [ensures] consistent interpretation of the same claim terms in the same patent.” Id.

IV. DISCUSSION

Applera argues that Bio-Rad’s amendment to the ’174 application in response to the PTO’s rejection of initially filed claims 1-13 triggers prosecution history estoppel as to claim 16 of the ’111 patent. Bio-Rad counters that prosecution history estoppel should not apply to claim 16 of the ’111 patent for several reasons. First, Bio-Rad argues that it overcomes any presumptive estoppel because the use of polyacrylamide would have been unforeseeable at the time of the amendment. Second, Bio-Rad argues that claim 16 of the ’111 patent does not contain the same limitation as initially filed claim 1 and thus should not be infected by any estoppel applied to initially filed claim 1. Finally, Bio-Rad argues that amending initially filed claim 1, without more, does not link claim 16 of the ’111 patent to initially filed claim 1 such that claim 16 should be subject to prosecution history estoppel.

A. Presumptive Prosecution History Estoppel

Bio-Rad amended the ’174 application in response to the PTO examiner’s obviousness rejection.¹ Obviousness, under 35 U.S.C. § 103, is a rejection based on patentability under the Patent Act. See

¹ Applera contends that the examiner rejected initially filed claim 1 and not initially filed claim 27 because claim 27 was limited to the members of its Markush group, none of which are polyacrylamide. Whereas initially filed claim 1 was limited only by a general description of the attributes of the claimed “substantially linear polymer.” Applera cites the examiner’s Statement of Reasons that issued with the Notice of Allowability for support of its position. Applera notes that the examiner drew particular attention to the Markush group in initially filed claim 27, now claim 16 and stated that even unamended, the claim avoided prior art references. Applera argues that the examiner’s statements imply that the absence of polyacrylamide in the Markush group was the reason it avoided the prior art. The Court notes that initially filed claim 27 appears, on its face, more specific than initially filed claim 1.

Festo VIII, 535 U.S. at 736. Bio-Rad's amendment to initially filed claim 1 changed the limitation "gel-free aqueous solution of a substantially linear polymer" to "gel-free aqueous solution of a substantially linear water-soluble cellulose derivative polymer." In both Warner-Jenkinson and Festo VIII the Supreme Court made "clear that a narrowing amendment may occur when either (1) a preexisting claim limitation is narrowed by amendment or (2) a new claim limitation is added by amendment." Honeywell Intern. Inc. v. Hamilton Sundstrand Corp., 370 F.3d 1131, 1140 (Fed. Cir. 2004)(citing Warner-Jenkinson Co. v. Hilton Davis Chemical Co., 520 U.S. 17, 30 (1997), and Festo VIII, 535 U.S. at 728). The addition of "water-soluble cellulose derivative" narrowed initially filed claim 1. Thus, Bio-Rad's amendment of initially filed claim 1 was "a narrowing amendment made to satisfy [the non-obviousness] requirement of the Patent Act [and] may give rise to an estoppel." Id.

Before determining whether Bio-Rad's amendment to initially filed claim 1 infects claim 16 of the '111 patent with prosecution history estoppel, the Court must determine whether prosecution history estoppel applies to initially filed claim 1 and whether Bio-Rad can overcome the presumption.

The effect of finding prosecution history estoppel is that the patentee presumptively surrenders his or her right to use the doctrine of equivalents to recapture "subject matter conceded during prosecution." Honeywell, 370 F.3d at 1141; Glaxo, 356 F.3d at 1351-52. Here, the PTO examiner rejected initially filed claim 1 because of prior art that "successfully performed molecular sieving experiments using non-crosslinked linear polyacrylamide." Garber Decl., Exh. 1, ABBR065889. In response, Bio-Rad gave up the more general limitation "gel-free aqueous solution of a substantially linear polymer," which includes polyacrylamide, for the more restrictive limitation "gel-free aqueous solution of a substantially linear water soluble cellulose derivative polymer," that does not include polyacrylamide. Thus, unless Bio-Rad can rebut the presumption, it is estopped from asserting that Applera's POP products infringe claim 1 of the '111 patent by way of the doctrine of equivalents.²

Bio-Rad argues that it overcomes any presumption of estoppel with regard to polyacrylamide because the use of polyacrylamide and PDMA, as it is used in the allegedly infringing products, was

²Indeed, Bio-Rad does not assert that claim 1 of the '111 patent is infringed by Applera's polyacrylamide-containing POP products.

unforeseeable at the time of Bio-Rad's amendment. If an "equivalent [was] unforeseeable at the time of the application . . . the patentee can overcome the presumption that prosecution history estoppel bars a finding of equivalence." Festo VIII, 535 U.S. at 740-41. The FCCA has explained that:

if the alleged equivalent represents later-developed technology (e.g. transistors in relation to vacuum tubes, or Velcro® in relation to fasteners) or technology that was not known in the relevant art, then it would not have been foreseeable. In contrast, old technology, while not always foreseeable, would more likely have been foreseeable. Indeed, if the alleged equivalent were known in the prior art in the field of the invention, it certainly should have been foreseeable at the time of the amendment.

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 344 F.3d 1359, 1369 (Fed. Cir. 2003) (Festo IX).

Bio-Rad argues that PDMA and polyacrylamide were not used in combination to electrophoretically separate ions until years after the '174 application was amended. Blanch Decl. ¶ 6. Bio-Rad also argues that the possibility of foreseeability is reduced because there were "well-known problems with using [polyacrylamide] in general as well as the inability to create the proper range of molecular weights for PDMA and mixtures of PDMA and polyacrylamide." Opposition, 18. Furthermore, Bio-Rad offers a list of mechanical problems, purity problems, manufacturing problems, toxicity problems, and implementation problems that it asserts would have made the use of PDMA or a combination of PDMA and polyacrylamide unforeseeable when initially filed claim 1 was amended.

This Court disagrees, however, that the use of PDMA or a combination of PDMA and polyacrylamide was sufficiently unforeseeable at the time of the amendment to overcome the presumption of estoppel. First, Bio-Rad's recitation of "well-known" problems with the use of polyacrylamide and PDMA does not necessarily suggest that it would have been unforeseeable at the time of the amendment that PDMA could represent an equivalent to the subject matter claimed in initially filed claim 1. Indeed, the fact that a chemical is difficult to manufacture or had not yet been used for the purpose claimed does not make it unforeseeable. Cf. Festo IX, 344 F.3d at 1369 (stating that transistors, in relation to vacuum tubes, represent an unforeseeable technology).

Second, the PTO examiner made his rejection based on prior art that used polyacrylamide in molecular sieving.³ Thus indicating that in drafting initially filed claim 1 with broad coverage of a “gel-free aqueous solution of a substantially linear polymer,” coverage of acrylamides was not only foreseeable, but accomplished. Thus, the Court finds that “at the time of the amendment one skilled in the art could . . . reasonably have been expected to have drafted a claim that would have literally encompassed the alleged equivalent.” Festo VIII, 535 U.S. at 733. Accordingly, the amendment to initially filed claim 1 imposes a presumption of prosecution history estoppel, which Bio-Rad is unable to overcome on grounds of unforeseeability.

B. Infectious Estoppel

Applera argues that the amendment to initially filed claim 1 creates an estoppel that should be applied to initially filed claim 27, now claim 16 of the ’111 patent. Bio-Rad contends that the estoppel should not be applied because the two claims do not contain the same limitation and there was no action by Bio-Rad in the course of the amendment that linked the claims in a way that requires the estoppel to be imposed on claim 16 of the ’111 patent.

Although Bio-Rad only amended initially filed claim 1, the same limitation, “gel-free aqueous solution of a substantially linear polymer,” was contained in initially filed claim 27. Garber Decl., Exh. 1, ABBR065864, ABBR065868. Bio-Rad argues that because initially filed claim 1 and initially filed claim 27 each claim different ionic separations the amendment to “claim 1 did not add the same limitation . . . that is present in unamended claim 16.” Opposition, 8. This argument, however, misses the point. Infectious estoppel is a mechanism employed to maintain the consistency of terms and limitations throughout a patent. Glaxo, 356 F.3d at 1356 (stating that infectious estoppel is a “quest for consistency” among claim terms). Both claims as initially filed and at the time of the amendment shared identical language. Insofar as the terms shared by the claims present identical limitations, this Court sees no reason why the terms of the

³ The Court ordered supplemental briefing on the issue of whether the accused polymers and Tietz’s polyacrylamide are different. After reviewing the parties’ submissions the Court is satisfied that the accused polymers are sufficiently similar to Tietz’s. Accordingly, the rejection based on Tietz suggests that at the time of the amendment the drafter of the ’111 patent could have drafted a claim that would have literally encompassed the accused products.

1 limitations would not have been construed alike. The two claims, although to different ionic separations,
2 contained the same limitation. Thus, initially filed claim 27, now claim 16 of the '111 patent does "recite the
3 amended term" and is subject to the same estoppel. Id.

4 Bio-Rad also argues that the estoppel does not apply to claim 16 of the '111 patent unless there
5 exists "some additional basis in combination with the narrowing amendment that justifie[s] infecting the
6 unamended claim with the same estoppel and Festo presumption as the [claim] that [was] amended to
7 include the same limitation." Opposition, 12. Bio-Rad cites Builders Concrete, Inc. v. Bremerton
8 Concrete Prods. Co., 757 F.2d 255 (Fed. Cir. 1985), for the proposition that prosecution history estoppel
9 is not limited to amendment based estoppel, but may arise in other ways, like argument based estoppel.
10 Bio-Rad then argues that the court in Glaxo relied on Builders and allowed the infectious estoppel because
11 the patentee failed to respond to the examiner's argument that the amended limitation was critical to all
12 claims. Id. (citing Glaxo, 356 F.3d at 1356.) Thus, according to Bio-Rad, both the amendment and the
13 argument were necessary bases for applying the infectious estoppel.

14 This Court does not read Glaxo to require an additional basis in combination with a narrowing
15 amendment before infecting an unamended claim with estoppel. Instead, it appears that the FCCA was
16 more concerned with the consistent interpretation of claim limitations than adding prerequisites to the
17 doctrine of prosecution history estoppel. See Glaxo, 356 F.3d at 1356 ("Thus, this court directs consistent
18 interpretation of claim terms within a patent in view of the prosecution history."); see also Am. Permahedge,
19 Inc. v. Barcana, Inc., 105 F.3d 1441, 1446 (Fed.Cir.1997) (stating that "identical claim terms used in
20 different claims must be interpreted consistently" and "under the doctrine of equivalents, we see no reason
21 to assign different ranges of equivalents for the identical term used in different claims in the same patent").
22 Although argument accompanying an amendment may indicate precisely what subject matter is
23 surrendered, argument is not a necessary basis for applying estoppel to an unamended claim.

24 The Court finds that Bio-Rad is estopped from asserting that Applera's POP products containing
25 polyacrylamide or PDMA are equivalents to, and thereby infringe, initially filed claim 27, now claim 16 of
26 the '111 patent. Bio-Rad may not use claim 16 of the '111 patent to recover the subject matter it
27 surrendered by amending initially filed claim 1.

V. CONCLUSION

For the reasons stated above the Court GRANTS Applera's Motion for Partial Summary Judgment.

Dated: August 12, 2005

/s/ James Ware
JAMES WARE
United States District Judge

1 THIS IS TO CERTIFY THAT COPIES OF THIS ORDER HAVE BEEN DELIVERED TO:

2 Alice Garber alice.garber@weil.com
3 Bobby A. Ghajar ghajarb@howrey.com
4 David Leon Bilsker bilskerd@howrey.com
5 Eugene Y. Mar eugene.mar@weil.com
6 Eugene Y. Mar eugene.mar@weil.com
7 Matthew D. Powers matthew.powers@weil.com
8 Thomas C. Mavrakakis mavrakakist@howrey.com
9 Tracy Jolles Holland hollandt@howrey.com
10 Vernon M. Winters vern.winters@weil.com
11 Wallace W. Wu wuw@howrey.com
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

Dated: August 12, 2005

Richard W. Wieking, Clerk

By: /s/ JW Chambers
Ronald L. Davis
Courtroom Deputy